Notice of Allowability	Application No. 09/660,862	Applicant(s) POLLACK, WILLIAM	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *29 December 2004*.
2. ☒ The allowed claim(s) is/are *1,5-9 and 14*, renumbered 1-7, respectively.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ALLOWANCE

1. This Office Action is responsive to Applicant's response December 29, 2004. All rejections of record are withdrawn in view of Applicant's amendment and remarks. Claims 1 and 5-9 are allowed. The claims have been renumbered as 1-7.

2. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests a method of manufacturing IgG4 immune globulin that has a decreased risk of aggregation and fragmentation, said method comprising (a) adjusting plasma to a pH of 6.5 and conductivity of between 3.5 to 6 millisiemens thereby obtaining a diluted plasma, (b) contacting the diluted plasma of step (a) with an anion exchange resin to obtain an anion exchange effluent and (c) contacting the effluent of step (b) with a cation exchange resin to obtain a cation exchange effluent that comprises IgG4 essentially free of other IgG subtypes.

3. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
March 11, 2005

L. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

CLEAN COPY OF CLAIMS

1. A method of manufacturing IgG4 immune globulin that has a decreased risk of aggregation and fermentation, said method comprising:(a) adjusting plasma to a pH of about 6.5 and a conductivity of between 3.5 to 6 millsiemens. thereby obtaining a diluted plasma; (b) contacting the diluted plasma of step (a) with an anion exchange resin to obtain an anion exchange effluent; and (c) contacting the effluent of step (b) with a cation exchange resin to obtain a cation exchange effluent that comprises IgG4 essentially free of other IgG subtypes.

2. The method of claim 1, further comprising the steps of:

(d) adding NaC1 to a final concentration of 0.03 to 0.05 M NaC1;

(e) filtering the solution of step (d);

(9 centrifuging the filtrate of step (e);

(g) freezing the supernatant of step (f);

(h) thawing the frozen supernatant of step (g);

(i) adding a monosaccharide or disaccharide to the thawed supernatant of step (h) to a final osmolarity of between 0.22 to 0.35 0sM;

(j) filtering the solution of step (i);

(k) freezing the filtered solution of step U);

(l) thawing the frozen solution of step (k); and

(m) lyophilizing the solution of step (l).

3. The method of claim 1, wherein said plasma is obtained from an immune donor.

4. The method of claim 1, wherein said anion exchange resin comprises Sepharose and a diethyl aminoethyl ion exchange group.

5. The method of claim 1, wherein said cation exchange resin comprises Sepharose and a carboxy methyl ion exchange group.

6. The method of claim 1, wherein said cation exchange effluent consist essentially of IgG4.

7. The method of claim 2, wherein said monosaccharide is lactose.